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| EXAMINER | |
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| SITTON, JEHANNE SOUAYA | |
| ART UNIT | PAPER NUMBER |
| 1634 | |

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/932,122 | BAKER, TONY | |
| | Examiner | Art Unit | |
| | Jehanne S. Sitton | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/16/2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Currently, claims 1-49 are pending in the instant application. On 5/2/2005, a petition to revive the instant application and amendment was filed. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are either newly applied, as necessitated by the submission dated 5/2/2005, or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The sequence listing submitted 5/2/2005 has been entered.

4. The amendments to claims 2, 14, 18, 30, 38, and 45 have overcome the objections made at sections 2 and 3 of the previous office action.

5. The amendments to the claims have overcome the rejections made under 35 USC 112/2$^{nd}$ paragraph made at section 5 A-E, of the previous office action.

6. The rejection of claims 37-47 under obviousness type Double Patenting over claims 21-24 of 09/805,785 is moot in view of the abandonment of the '785 application.

***Maintained Rejections***

***Claim Rejections - 35 USC § 102***

7. Claims 1-8, 14, 15, 17-24, 30, 36-43, and 45, 46, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Chung et al (Mol Cells. Vol. 6, pp 108-111, 1996).

The claims are drawn to a method of suppressing the interference of a masking agent on a molecular assay of a nucleic acid containing test sample or a method of improving the signal response of a molecular assay by suppressing the interference of a masking agent on a molecular assay of a nucleic acid containing test sample, or a method of improving hybridization of nucleic acids comprising contacting the test sample with an amount of a divalent metal chelator and a chelator enhancing component. Claim 17 is further drawn to extracting molecular analytes of interest from the sample, and conducting a molecular assay on the extracted molecular analytes. With regard to claim 37, the recitation of "test nucleic acid" and "target nucleic acid" are interpreted to be any nucleic acid molecule, respectively

With regard to claims 1, 17, and 37, Chung et al teach an improved method of isolating quality polysaccharide free RNA from plant tissues by 1) adding an extraction buffer (buffer A; limitations of claims 2-8, 14, 18-24, 30, 38-43, and 45) comprising 300 mM (0.3M) LiCl and 10mM (0.01M) EDTA and 1.5% SDS to a sample (test sample containing nucleic acid) of pulverized sesame and perilla oilseeds (see p. 109, col. 1, "Solutions", "Procedure"), 2) extracting RNA (extracting molecular analytes of interest) (p. 109, cols 1 and 2 "procedure"), and 3) spectrophotometrically and electrophoretically (p. 109, last para, table 1, Figure 1) assessing the quality and quantity of extracted RNA, Northern Hybridization (fig 2), and RT-PCR with the RNA (conducting a molecular assay on the extracted molecular analytes of

interest). Chung specifically teaches that the quality of RNA was dependent on the RNA extraction buffer used and that buffer A greatly enhanced the RNA quality isolated from oilseeds of sesame and perilla (p. 110, col. 1, lines 1-4). Table 1 of Chung teaches enhanced absorbance ratios (improved signal response) and Figure 1 of Chung teaches clearer bands on an agarose gel with the use of buffer A. Claims 36 and 48 are drawn to the method wherein the molecular assay is PCR. Chung teaches constructing cDNA libraries from RNA populations acquired using buffer A, and that northern hybridization using cDNA probes showed that the RNA isolated was intact and functional (page 111- first para, figure 2), therefore Chung inherently teaches an RT-PCR method with improved signal (figure 2) (in this case, "signal response" is broadly interpreted to encompass intact and functional cDNA derived from isolated RNA using buffer A and "improved hybridization" is broadly interpreted to encompass Northern hybridization in figure 2 with the improved quality RNA as well as hybridization of primer to target in the RT-PCR with improved signal).

***Response to Arguments***

8. The response traverses the rejection. The response asserts that Chung does not teach suppression of a masking agent as there is no discussion of any of the masking agents contemplated in the present specification and that the teachings of Chung does not inherently involve freeing the RNA from the masking agents of the type recited in the claims. This argument has been thoroughly reviewed but was not found persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., specific masking agents in the specification as well

as in claims 10-13 and 26-29) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). At page 5, the specification defines a masking agent or interferent of a molecular assay as including compounds which interfere or otherwise affect the accuracy of the assay, masking the true or detectable amount of the nucleic acid in the sample. The specification's recitation of leukocyte esterases, heme proteins, etc, are examples of masking agents, they do not provide an express definition of a masking agent and therefore are not read into the claims. Claims 10-13 and 26-29, which recite these specific masking agents, were not included in this rejection. Further, the specification provides no express definition of a molecular assay and instead states that the invention relates generally to DNA analysis (page 1), assays of nucleic acids in bodily samples (page 3), hybridization assays (page 3), probe based diagnostics, microarray/Chip methods, PCR, amplification, SNP analysis, DNA sequencing, drug discovery, drug response genes, (page 4, lines 19-22), NASBA, SDA, and genetic transformation testing (page 5). As such, no specific definition is given. Instead, the specification provides very broad and general teachings of molecular assays, and therefore the term "molecular assay" can be broadly and reasonably interpreted to be any assay involving DNA. Therefore, the recitations of the instant broadly recited pending claims do not distinguish over the teachings of Chung. The response asserts that Chung does not disclose 'suppressing the interference of a masking agent of a molecular assay of a nucleic acid containing test sample'. This argument has been thoroughly reviewed but was not found persuasive as the claims do not recite any specific suppression, nor does the specification provide any definition for such term. Therefore, the term's broadest reasonable interpretation is

the removal of such interference, in any manner, such that the interference or masking is no longer there. The response further asserts the assay for DNA purity ($A_{260}/A_{280}$ determination) taught by Chung, cannot by itself be taken to indicate suppression of interference from a potential masking agent as many masking agents are non protein and do not necessarily absorb ultraviolet light in the relevant wavelength and may still be present. This argument has been thoroughly reviewed but was found unpersuasive because the claim does not require the suppression of all possible masking agents. Additionally, Chung specifically teaches that the quality of RNA was dependent on the RNA extraction buffer used and that buffer A greatly enhanced the RNA quality isolated from oilseeds of sesame and perilla (p. 110, col. 1, lines 1-4). Chung teaches assessing the quality and quantity of extracted RNA, Northern Hybridization (fig 2), and RT-PCR with the RNA (conducting a molecular assay on the extracted molecular analytes of interest). Table 1 of Chung teaches enhanced absorbance ratios (improved signal response) and Figure 1 of Chung teaches clearer bands on an agarose gel with the use of buffer A. Claims 36 and 48 are drawn to the method wherein the molecular assay is PCR. Chung teaches constructing cDNA libraries from RNA populations acquired using buffer A, and that northern hybridization using cDNA probes showed that the RNA isolated was intact and functional (page 111- first para, figure 2), therefore Chung inherently teaches an RT-PCR method with improved signal (figure 2) (in this case, "signal response" is broadly interpreted to encompass intact and functional cDNA derived from isolated RNA using buffer A). The response asserts that there is no teaching in Chung of improving hybridization of nucleic acids and that the demonstration of intact and functional cDNA does not necessarily and inevitably lead to the conclusion that hybridization has improved. This argument has been thoroughly

reviewed but was found unpersuasive. Chung specifically teaches that high quality RNA is essential for Northern hybridization (see page 108, col. 1, first sentence), and that polysaccharide contaminated RNA compositions are not suitable for such molecular procedures. Chung teaches a buffer composition (buffer A) that allowed for high quality RNA isolation, and teaches that specifically given the results of a northern hybridization assay(figure 2), the RNA obtained using buffer A was assumed to be intact and functional. For these reasons and the reasons already made of record, the rejection is maintained.

9. Claims 1-6, 8-9, 15-16, 37-41, 43-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang (WO 95/35390; 12/28/1995).

The claims are drawn to a method of suppressing the interference of a masking agent on a molecular assay of a nucleic acid containing test sample or a method of improving hybridization of nucleic acids comprising contacting the test sample with an amount of a divalent metal chelator and a chelator-enhancing component. With regard to claim 37, the recitation of "test nucleic acid" and "target nucleic acid" are interpreted to be any nucleic acid molecule, respectively.

With regard to claims 37-41 and 43-47, Zhang teaches a method comprising adding a lysis buffer containing 2.5-5M guanidine thiocyanate and 100mM EDTA to an equal volume of sample (eg serum) that contains nucleic acids (test nucleic acids) (it is noted that the final concentration of buffer would be 1.25-2.5 M GnSCN and .05M EDTA) (p. 14, lines 8-30), and subsequently adding nucleic acid amplification probes (target nucleic acid) and paramagnetic beads to the solution containing lysis buffer and nucleic acids from the sample. Zhang

specifically teaches that hybridization occurs between the nucleic acid from the sample and the probes (p.17, lines 19-20). Zhang specifically teaches that the method can be used for detection of genetic variations in samples from patients with genetic diseases or neoplasia (page 4, lines 13-23, page 5, lines 12-19- eukaryotic DNA). It is noted that the preamble is drawn to "a method of improving hybridization of nucleic acids". However, the recitation of "improve hybridization of nucleic acids" does not carry patentable weight to overcome the teachings of Zhang as Zhang teaches the positive process steps of the claimed method in the same order.

With regard to claim 1, Zhang teaches that the complex comprising target nucleic acid probes is separated by means of a magnetic field and that the complex is washed 2-3 times with a wash buffer comprising 1-1.5 M GnSCN and 10 mM EDTA (claims 2-6, 8-9) which removes unbound proteins, nucleic acids, and probes that may interfere with subsequent steps (suppressing the interference of a masking agent) (see para bridging pp 17-18).

***Response to Arguments***

10. The response traverses the rejection. The response asserts that the removal of unbound proteins, nucleic acids, or probes that interfere with subsequent steps cannot be equated with the removal of a masking agent and that there is no teaching or suggestion in Zhang of the removal of a masking agent as defined in the specification. This argument has been thoroughly reviewed but was found unpersuasive. The response provides no reasoning as to why Zhang's teaching of the removal of proteins, nucleic acids, or probes that would interfere with subsequent steps in Zhang's molecular assay involving nucleic acid ligation (a molecular assay involving DNA) "cannot be equated with the removal of a masking agent", therefore it is assumed that such

statement was made because Zhang does not specifically recite "removal of a masking agent". However such is not found persuasive as Zhang specifically teaches that the buffer containing 1-1.5 M Guanidine Thiocyanate and 10 mM EDTA (instantly claimed composition), was used for removal of agents (proteins, nucleic acids, probes) that would interfere with Zhang's molecular assay. The instant specification teaches that masking agents are "compounds which *interfere* or otherwise *affect the accuracy* of the assay, masking the true or detectable amount of nucleic acid in the sample" (page 5), which is taught by Zhang. The fact that Zhang does not use the term "masking agent" is not sufficient to distinguish the instantly claimed invention from the teachings of Zhang. The response asserts that the preamble must be given weight as it gives life, meaning, and vitality to the claim. This argument has been thoroughly reviewed but was found unpersuasive. In the instant case, Zhang teaches the positive process steps of the claimed method in the same order, and the reagents and concentrations used in the method of Zhang are encompassed by instant claims. Therefore, the teachings of Zhang (which include assays which use hybridization) would necessarily improve hybridization because the teachings of Zhang are the same as that of the instantly claimed invention. It is noted that claim 37 simply recites that the amounts of divalent metal chelator and chelator enhancing component are selected such that hybridization is improved. The amounts of Zhang's divalent metal chelator and chelator enhancing component are encompassed by the instant pending claims, and therefore Zhang inherently teaches such amounts. Further, claim 37 recites contacting the test solution with target nucleic acid such that hybridization occurs, which is also taught by Zhang. Therefore, Zhang teaches the positive process steps of the claimed method in the same order, and the preamble of the instantly pending claims does not provide meaning into the recited claim to

distinguish the instantly pending claims from the teachings of Zhang. For these reasons and the reasons already made of record, the rejection is maintained.

11. Claims 1-3, 6, 10-19, 22, 26-32 and 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Harvey et al (US Patent 6,168, 922; 102(e) date: 4/9/1997) as defined by Akane et al (Forensic Science, vol. 39, pp 362-372, 1994). (It is noted that the following rejection also applies to claims 1-3, 10, 12-19, 22, 26, 28-32, and 34-36 under 35 USC 102(a) as the claims have not been awarded the benefit of the priority of parent application 09/185,402 as the '402 application does not provide support for "suppressing a masking agent or suppressing the interference of a masking agent, or such masking agents as leukocyte esterases, and bilirubin. Claims 11 and 27 have been awarded the benefit of the filing date of the '402 application as the application states that the reagent concentrations were found to modulate the effect of hemoglobin, mathemoglobin. This disclosure does not provide support for the broader claims, as hemoglobin and mathemoglobin are not considered to exemplify any 'masking agent').

The claims are drawn to a method of suppressing the interference of a masking agent on a molecular assay of a nucleic acid containing test sample or a method of improving the signal response of a molecular assay by suppressing the interference of a masking agent on a molecular assay of a nucleic acid containing test sample comprising contacting the test sample with an amount of a divalent metal chelator and a chelator enhancing component. Claim 17 is further drawn to extracting molecular analytes of interest from the sample, and conducting a molecular assay on the extracted molecular analytes. It is noted that the claims are not drawn to

embodiments where the divalent metal chelator and chelator-enhancing component are added together or in a solution.

Harvey et al teach and claim methods and devices for collecting, storing, and purifying nucleic acids such as DNA or RNA from fluid samples for subsequent genetic characterization by conventional amplification methods (see abstract, claims 1-34). Harvey et al specifically teach that the nucleic acids can be either from an untreated blood source such as saliva, serum or urine, or a treated blood source (see abstract, col. 2, lines 54-65) that has naturally occurring nucleic acid amplification inhibitors present, such as hemoglobin. Harvey et al teach that the device, 903 paper, should be composed of an absorbent material that does not bind nucleic acids irreversibly, impregnated with a chaotropic salt such as guanidine isothiocyanate or sodium perchlorate. Harvey et al specifically teach a method whereby a square of treated paper (treated with guanidine thiocyanate – see example 1, col. 5) is added to blood which has been collected in a tube containing EDTA (see example 6). Harvey et al teach that DNA was extracted from the paper and subjected to PCR (see figure 7, lanes 9 and 10 which show amplification of product). It is noted that Harvey et al does not teach suppressing the effects of methemoglobin, however such is considered a component of blood samples along with hemoglobin and other oxidation and breakdown products thereof. Hemoglobin was known to inhibit PCR reactions at the time of the invention. Further, such inhibition was known to be caused by heme (see Akane et al), which is a component of methemoglobin.

***Response to Arguments***

12. The response traverses the rejection. The response asserts that there is no basis for the position taken by the office that the '402 application does not provide support for the recitation of a masking agent in general. The response asserts that hemoglobin and mathemoglobin are typical masking agents and that it is well understood that not all specific examples of a compound that has a particular activity or properties be recited in the specification for there to be support for a more general recitation of a compound having such activity or properties. This argument has been thoroughly reviewed but was found unpersuasive. The MPEP at 2163.03, II, states "Under 35 USC 120, the claims in a U.S. application are entitled to the benefit of the filing date of an earlier filed US application if the subject matter of the claim is disclosed in the manner provided by 35 USC 112, first paragraph in the earlier filed application". Additionally, the MPEP at section 2163.05, states "... in *Tronzo v. Biomet*, 156 F.3d 1154, 1159, 47 USPQ2d 1829, 1833 (Fed. Cir. 1998), the disclosure of a species in the parent application did not suffice to provide written description support for the genus in the child application. Similarly, see *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (generic and subgeneric claims in the U.S. application were not entitled to the benefit of foreign priority where the foreign application disclosed only two of the species encompassed by the broad generic claim and the subgeneric Markush claim that encompassed 21 compounds). The '402 application does not recite the broad generic term "masking agent", nor does it provide support for "suppressing a masking agent" or suppressing the interference of a masking agent, or such masking agents as leukocyte esterases, and bilirubin. As is exemplified by the definition in the instant specification, a masking agent is defined at page 5 as "compounds which *interfere* or otherwise *affect the accuracy* of the assay,

masking the true or detectable amount of nucleic acid in the sample", which can include other proteins than the heme containing proteins hemoglobin and mathemoglobin, as well as other types of molecules such as carbohydrates, nucleic acids, etc. The response itself, at page 17, states that many masking agents are non protein. The term thus encompasses a large genus of structurally and functionally distinct molecules, which are not represented either structurally or functionally by hemoglobin or mathemoglobin. The term "masking agent" and suppression of any "masking agent" or suppression of the interference of any "masking agent" thus represents a broadening of the invention in the '402 application and does not find support in the '402 application under the written description requirement of 35 USC 112, first paragraph.

The response further asserts that Harvey does not teach the claimed invention because Harvey does not teach adding the required components to a test sample as is used in the specification and the claims because the nucleic acid is applied to absorbent paper and that the nucleic acid must be released from the support to create a test sample. This argument has been thoroughly reviewed but was found unpersuasive. The instant specification does not provide a specific definition for a "test sample" but the term "sample" is defined as substances containing or presumed to contain nucleic acid, including bodily fluids (page 6). Further, the instantly rejected claims simply recite that the test sample is contacted with an amount of a divalent metal chelator (dependent claims include EDTA) and a chelator enhancing component (dependent claims include guanidine), which is taught by Harvey (see example 6, blood – test sample containing nucleic aid- is collected in a tube containing EDTA –divalent metal chelator- and a square containing guanidine –chelator enhancing component- is added). Therefore, Harvey specifically teaches contacting a test sample with a chelator and chelator enhancing component

and anticipates the instantly pending claims. For these reasons and the reasons already made of record, the rejection is maintained. [It is noted that the previous office action and applicant's response contained a typographical error and referred to the parent application as 09/185,401 or '401 (09/185,*402* is the correct number). For the purposes of providing a clear record, this typographical error has been corrected in the instant office action.]

***Claim Rejections - 35 USC § 103***

13. Claims 7 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harvey et al.

Harvey et al teach and claim methods and devices for collecting, storing, and purifying nucleic acids such as DNA or RNA from fluid samples for subsequent genetic characterization by conventional amplification methods (see abstract, claims 1-34). Harvey et al specifically teach that the nucleic acids can be either from an untreated blood source such as saliva, serum or urine, or a treated blood source (see abstract, col. 2, lines 54-65) that has naturally occurring nucleic acid amplification inhibitors present, such as hemoglobin. Harvey et al teach that the device, 903 paper, should be composed of an absorbent material that does not bind nucleic acids irreversibly, impregnated with a chaotropic salt such as guanidine isothiocyanate or sodium perchlorate. Harvey et al specifically teach a method whereby a square of treated paper (treated with guanidine thiocyanate – see example 1, col. 5) is added to blood which has been collected in a tube containing EDTA (see example 6). Harvey et al teach that DNA was extracted from the paper and subjected to PCR (see figure 7, lanes 9 and 10 which show amplification of product). Harvey does not specifically exemplify paper treated with sodium perchlorate, however Harvey

et al teach that such would be a suitable chaotropic agent. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the device of Harvey et al, treated with sodium perchlorate as Harvey et al teach that such would be a suitable device (see col. 3, lines 16-36) for use in the method of Harvey et al.

***Response to Arguments***

14. The response traverses the rejection. The response asserts that all claim limitations must be considered in evaluating non-obviousness of an invention in light of the prior art and that as indicated previously, Harvey does not teach the use of the agents taught by Harvey in a test sample. This argument has been thoroughly reviewed but was not found persuasive for the reasons made of record above. As noted previously, Harvey teaches a method whereby a test sample containing nucleic aid- is collected in a tube containing EDTA –divalent metal chelator- and a square containing a chaotropic agent –chelator enhancing component- is added. Although Harvey does not specifically exemplify 903 paper with sodium perchlorate, Harvey et al teach that the device, 903 paper, should be composed of an absorbent material that does not bind nucleic acids irreversibly, impregnated with a chaotropic salt such as sodium perchlorate. For these reasons and the reasons already made of record, the rejection is maintained.

15. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chung or Sigman, or Harvey et al (in the alternative), each in view of Ahern (The Scientist; vol. 9, pp 1-5- from the internet; 1995).

Chung et al teach an improved method of isolating quality polysaccharide free RNA from plant tissues by 1) adding an extraction buffer (buffer A) comprising 300 mM (0.3M) LiCl and 10mM (0.01M) EDTA and 1.5% SDS to a sample. Chung teaches performing RT-PCR on RNA isolated using said buffer.

Sigman teaches a method of isolating and preserving DNA. Sigman teaches that there is a need to isolate and prevent degradation of DNA in blood samples from patients suspected of infection with parasites, such as T. Cruzi (eukaryotic DNA) or other infectious agents during storage (p. 3, lines 16-19). Sigman teaches that isolation and storage comprise contacting a biological sample containing DNA in cells with a buffer (aqueous solution) containing a nonamphipathic chaotropic salt (chelator enhancing component) such as guanidine thiocyanate or guanidine chloride and a concentration of a chelating agent. Sigman teaches performing PCR with the preserved nucleic acid.

Harvey et al teach and claim methods and devices for collecting, storing, and purifying nucleic acids such as DNA or RNA from fluid samples for subsequent genetic characterization by conventional amplification methods (see abstract, claims 1-34). Harvey et al teach that the device, 903 paper, should be composed of an absorbent material that does not bind nucleic acids irreversibly, impregnated with a chaotropic salt such as guanidine isothiocyanate or sodium perchlorate. Harvey et al specifically teach a method whereby a square of treated paper (treated with guanidine thiocyanate – see example 1, col. 5) is added to blood which has been collected in a tube containing EDTA (see example 6). Harvey et al teach that DNA was extracted from the paper and subjected to PCR.

Neither Chung nor Sigman nor Harvey et al teach the reagents or device in kit format, however Ahern teaches that providing reagents and products in kit offer scientists the opportunity to better manage their time, and that such kits are convenient. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to package the reagent of Chung or Sigman, or the device of Harvey et al in kit format for the purposes of providing premade reagents which are convenient and will save researchers time, as taught by Ahern.

***Response to Arguments***

16. The response traverses the rejection. The response asserts that since neither Chung, Sigman, nor Harvey teach suppression of interference by a masking agent in a molecular assay such as PCR, the primary references in combination with Ahern fail to teach or suggest the invention in it's entirety. This argument has been thoroughly reviewed but was found unpersuasive as the use for a kit carries no patentable weight. The kit is simply recited to include a reagent which suppresses the interference of a masking agent. The reagents taught by Chung, Sigman, and Harvey are reagents which would suppress the interference of a masking agent on a molecular assay. The packaging of such kits is obvious over the teachings of Chung, or Sigman, or Harvey, each in view of Ahern, as set forth above. The instructions in the instantly claimed kit are considered printed material and are not given patentable weight. The inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004) (holding that an inventor could

not patent known kits by simply attaching new set of instructions to that product). For these reasons and the reasons already made of record, the rejection is maintained.

***Double Patenting***

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,458,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are coextensive in scope. The claimed method steps of the instant application encompass the more narrow methods steps of the claims of the '546 patent. The claims of the '546 patent do not recite a method of suppressing a masking agent, however, the claims are drawn to a method of preserving a nucleic acid in a bodily fluid by adding a reagent containing, for example, EDTA and guanidine thiocyanate to a bodily fluid. Guanidine thiocyanate is a chaotropic agent known to inhibit proteases, therefore, suppressing a masking agent such as a nuclease (which would

mask the amount of nucleic acid in a sample by degrading it) is considered a property of the claimed method of the '546 patent.

***Response to Arguments***

19. The response traverses the rejection. The response asserts that the claims of the '546 application do not recite a method of suppressing a masking agent and that preservation of a sample cannot necessarily be equated with a masking agent. This argument has been thoroughly reviewed but was found unpersuasive as the method steps used in each method are coextensive in scope. The claimed method steps of the instant application encompass the more narrow methods steps of the claims of the '546 patent. The instantly claimed invention encompasses addition of an amount of guanidine, lithium chloride, sodium salicylate, sodium perchlorate or sodium thiocyanate, and an amount of EDTA, EGTA, or BAPTA to a bodily fluid containing nucleic acid. Claim 1 of the '546 patent is drawn to adding an amount of guanidine, lithium chloride, sodium salicylate, sodium perchlorate or sodium thiocyanate, and an amount of EDTA, EGTA, or BAPTA to a bodily fluid to. It is further noted that instant dependent claims 4 and 8 are drawn to concentrations that are recited in the preservative solution of claim 1 of the '546 patent. As guanidine isothocyanate is a chaotropic agent which would inhibit nucleases, the suppression of a masking agent is considered a property of the claimed method of the '546 patent. For these reasons and the reasons already made of record, the rejection is maintained.

20. Claims 17-36 and 48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,458,546 in view of Sigman.

The instant claims are drawn to a method of improving the signal response of a molecular assay by interfering with a masking agent by adding a divalent metal chelator (further drawn to adding such in solution in the range of from about 0.001M to 0.1M) and a chelator enhancing component (further drawn to adding such in solution in the range of from about 0.1M to 2M) to a test sample, which can be a biological fluid, extracting molecular analytes of interest from the sample, and conducting a molecular assay on the extracted molecular analytes. Claims 1-8 of the '546 patent are drawn to preserving nucleic acids in a biological fluid by contacting the biological fluid with a solution containing a divalent metal chelator in the range of from about 0.001M to about 0.1M and a chelator enhancing component in the range of from about 0.1M to about 2M. Although the claims of the '546 patent do not disclose extracting the nucleic acids and conducting a molecular assay on the extracted nucleic acids, Sigman teaches a method of isolating and preserving DNA and extracting the isolated and preserved DNA to perform molecular assays, such as hybridization and PCR on the extracted DNA (p. 3, lines 16-19). Sigman specifically teaches that the DNA was extracted (extracting molecular analytes of interest) and electrophoresed (conducting a molecular assay) and T.cruzi nucleic acids were identified. Sigman teaches that there is a need to prepare the DNA for amplification (p. 3, lines 20-21). Sigman specifically teaches a polymerase chain reaction on cleaved minicircle DNA extracted from a blood/GnCl/ EDTA (GEB lysate) sample (see examples 3 and 4). Sigman teaches that using the GEB lysate, PCR amplification of extracted minicircles was sensitive enough that a single T.cruzi cell could be detected in 20 ml of blood (p. 35). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to extract and assay the nucleic acids preserved in the claims of the '546 patent for the

purpose of sequencing, or identifying the origin of the DNA preserved, for example to identify infective pathogens in a sample of blood from a patient as taught by Sigman. The ordinary artisan would have been motivated to extract and assay the nucleic acids preserved in the method of the '546 patent for the purpose of identifying such nucleic acids for diagnosing a pathogenic infection, for example. Guanidine thiocyanate is a chaotropic agent known to inhibit proteases, therefore, suppressing a masking agent such as a nuclease (which would mask the amount of nucleic acid in a sample by degrading it) is considered a property of the claimed method of the '546 patent.

***Response to Arguments***

21. The response traverses the rejection. The response asserts that for the reasons already given, Sigman does not disclose or suggest the suppression by a masking agent or the improvement of a signal response due to the suppression of interference by a masking agent, the combination of Baker and Sigman does not provide basis for the rejection. This argument has been thoroughly reviewed but was not found persuasive for the reasons made of record in the rejection above as well as with regard to the '546 patent in section 19, and Sigman in section 25 of the instant office action.

22. Claim 49 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,458,546 in view of Ahern. Claims 1-8 of the '546 patent are drawn to preserving nucleic acids in a biological fluid by contacting the biological fluid with a solution containing a divalent metal chelator in the range of from about 0.001M to about 0.1M and a chelator enhancing component in the range of from

about 0.1M to about 2M. Although the claims of the '546 patent do not disclose the preservative solution in kit format, Ahern teaches that providing reagents and products in kit offer scientists the opportunity to better manage their time, and that such kits are convenient. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to package the reagent of the '546 patent in kit format for the purposes of providing premade reagents which are convenient and will save researchers time, as taught by Ahern. It is noted that the "use for" the kit carries no patentable weight. Guanidine thiocyanate is a chaotropic agent known to inhibit proteases, therefore, suppressing a masking agent such as a nuclease (which would mask the amount of nucleic acid in a sample by degrading it) is considered a property of the preservative solution recited in the claimed methods of the '546 patent.

***Response to Arguments***

23. The response traverses the rejection. The response asserts that there is no teaching of the kit of claim 49 when claims 1-8 of the '546 patent and Ahern are combined as the claims 1-8 of '546 patent do not teach or suggest suppression of a masking agent. This argument has been thoroughly reviewed but was found unpersuasive because the use for the kit carries no patentable weight. The kit is simply recited to include a reagent which suppresses the interference of a masking agent. The reagents taught by '546 claims are reagents which would suppress the interference of a masking agent on a molecular assay. The packaging of such kits is obvious over the teachings of claims 1-8 of the '546 patent, in view of Ahern, as set forth above. The instructions in the instantly claimed kit are considered printed material and are not given

patentable weight. The inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004) (holding that an inventor could not patent known kits by simply attaching new set of instructions to that product). For these reasons and the reasons already made of record, the rejection is maintained

***New Grounds of Rejection***

24. Claims 1-6, 8, 9, 15-22, 24, 25, 31-41, 43-44, and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Sigman et al (WO 93/03167, 2/18/1993).

The claims are drawn to a method of suppressing the interference of a masking agent on a molecular assay of a nucleic acid containing test sample or a method of improving the signal response of a molecular assay by suppressing the interference of a masking agent on a molecular assay of a nucleic acid containing test sample, or a method of improving hybridization of nucleic acids comprising contacting the test sample with an amount of a divalent metal chelator and a chelator enhancing component. Claim 17 is further drawn to extracting molecular analytes of interest from the sample, and conducting a molecular assay on the extracted molecular analytes. With regard to claim 37, the recitation of "test nucleic acid" and "target nucleic acid" are interpreted to be any nucleic acid molecule, respectively.

With regard to claims 1, 17, and 37, Sigman teaches a method of isolating and preserving DNA. Sigman teaches that there is a need to isolate and prevent degradation of DNA in blood samples from patients suspected of infection with parasites, such as T. Cruzi (eukaryotic DNA;

claims 15-16, 34-35, and 46-47) or other infectious agents during storage (p. 3, lines 16-19). Sigman teaches that isolation and storage comprise contacting a biological sample containing DNA in cells with a buffer (aqueous solution) containing a nonamphipathic chaotropic salt (chelator enhancing component) such as guanidine thiocyanate or guanidine chloride (claims 6 and 23) and a concentration of a chelating agent (divalent metal chelator; claims 2, 3, 18, 19, 38, and 39) such as EDTA (see p. 9, lines 1-11). Sigman teaches that the method is suitable for use on any biological sample including human blood, urine, sputum and lymphatic fluid (claims 31-33) (p. 12, lines 15-21). Sigman teaches that preferably, the guanidinium chloride is present in at least 3 molar concentration (this concentration anticipates claim 8 [and 24] as the range in claim 8 recites a 20 fold difference in concentration, such that 'about' 0.1-2M is broadly interpreted to encompass 3 M; with regard to amended claims 9 and 25, "at least about 1M" is interpreted to encompass a minimum of about 1M with a maximum concentration above "about 1M" as limited by the upper limitation in claim 8, which includes 3M) and the chelating agent in at least 0.1 molar concentration (claims 4, 20, and 40) in the mixture of the biological sample and storage buffer (with regard to claims 5, 21, and 41, Sigman teaches a solution that contains a divalent metal chelator in an amount of at least about 0.01M). Sigman specifically teaches that human intravenous blood was freshly drawn and added to a tube containing guanidinium chloride and EDTA so that the final concentration of each was 3M and .1M respectively (p. 26, Example 1). Sigman teaches that the DNA was extracted (extracting molecular analytes of interest) and electrophoresed (conducting a molecular assay) and that the DNA stored in a mixture of the buffer remains intact at 37 deg. C for at least a month (page 27 and Figure 1). As Sigman teaches that there is a need to prevent DNA degradation in blood samples (p. 3, lines 16-

20), the method of Sigman inherently improves the signal response of the electrophoresis step taught by Sigman in example 1 as the intact DNA bands visible on the gel is an inherent improvement over the smear of DNA that would be observed should the DNA have been degraded. Preventing such degradation inherently suppresses the interference of a masking agent, such as a nuclease which would degrade the DNA. With regard to claims 36 and 48, Sigman teaches that there is a need to prepare the DNA for amplification (p. 3, lines 20-21). Sigman specifically teaches a polymerase chain reaction on cleaved minicircle DNA extracted from a blood/GnCl/ EDTA (GEB lysate) sample (see examples 3 and 4). Sigman teaches that using the GEB lysate, PCR amplification of extracted minicircles was sensitive enough that a single T.cruzi cell could be detected in 20 ml of blood (p. 35). With regard to claim 37, the method of Sigman is interpreted to improve hybridization of primers to intact DNA as compared to hybridization that would occur with regard to degraded DNA.

***Response to Arguments***

25. The response traverses the rejection. The response asserts that Sigman does not specifically disclose the interference of a masking agent and that therefore, any suppression of interference is unintentional and inadvertent and therefore cannot anticipate the claimed invention. This argument has been thoroughly reviewed but was found unpersuasive. Firstly, the mixture used by Sigman was specifically taught to be used to isolate and preserve the DNA for future use. Therefore, the suppression of interference by a masking agent, such as nuclease, was not inadvertent or unintentional. Sigman, at page 3, specifically teaches use of a buffer containing the claimed components to preserve the DNA from degradation. Secondly, as stated

in the MPEP, section 2112 II: "There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference." The response's assertion that the term "molecular assay", in light of the specification, must be read to mean an assay in which sequence specific recognition plays some role is not found persuasive. Sigman does teach assays in which sequence specific recognition plays a role (PCR). Further, the specification provides no express definition of a molecular assay and instead states that the invention relates generally to DNA analysis (page 1), assays of nucleic acids in bodily samples (page 3), hybridization assays (page 3), probe based diagnostics, microarray/Chip methods, PCR, amplification, SNP analysis, DNA sequencing, drug discovery, drug response genes, (page 4, lines 19-22), NASBA, SDA, and genetic transformation testing (page 5). As such, no specific definition is given. Instead, the specification provides very broad and general teachings of molecular assays, and therefore the term "molecular assay" can be broadly and reasonably interpreted to be any assay involving DNA. The response's assertion that Sigman does not teach or disclose improvement in hybridization because Sigman focuses on methods by which DNA is subject to chemical cleavage and that anticipation is unintended and accidental is not found persuasive. As already noted above, the mixture used by Sigman was specifically taught to be used to isolate and preserve the DNA for future use, such as PCR - which uses hybridization. Therefore, the suppression of interference by a masking agent, such as nuclease, was not inadvertent or unintentional. Sigman, at page 3, specifically teaches use of a buffer containing the claimed components to preserve the DNA from degradation. Also, as stated in the MPEP, section 2112 II: "There is no requirement that a person of ordinary skill in the art would have recognized the

inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference." The response also asserts that prevention of degradation by a nuclease cannot be equated with suppression of interference of a masking agent because most masking agents do not act to degrade DNA. This argument has been thoroughly reviewed but was found unpersuasive. The specification defines a masking agent as "compounds which interfere or otherwise affect the accuracy of an assay, masking the true or detectable amount of the nucleic acid in the sample". The presence of a nuclease which would degrade a nucleic acid in a sample which contains nucleic acid, would mask the true or detectable amount of nucleic acid in the sample. The fact that many masking agents are not nucleases does not change the property of the nuclease. The specification does not exclude nucleases as masking agents. The response's interpretation of "suppression of interference with a masking agent" represents further invention after the time of filing, which is not basis for withdrawal of the rejection.

26. Claim 49 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of copending Application No.11/138,543. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 49 of the instant application is drawn to a kit that comprises a reagent for suppressing the interference of a masking agent on a molecular assay and instructions for use. As defined by the specification such a reagent includes a divalent metal chelator, such as EDTA, EGTA, or BAPTA, and/or a chelator enhancing component, such as lithium chloride, guanidine, sodium thiocyanate, sodium salicylate, and sodium perchlorate. Claim 19 of the '543

application is drawn to a kit comprising a preservative composition comprising an amount of a divalent metal chelator, such as EDTA, EGTA, or BAPTA, in the range of about .001M to 2 M and a chelator enhancing component, such as lithium chloride, guanidinium chloride, guanidinium thiocyanate, sodium thiocyanate, sodium salicylate, and sodium perchlorate, in the range of from about 0.1M to 10 M; a vessel for collecting a fluid; and instructions for use. It is noted that claim 19 of the '543 application is sufficiently broad such that the vessel could contain the preservative composition. The vessel is not recited to contain any specific composition and is not limited to containing a bodily fluid. As such, although instant claim 49 does not recite a container, the reagent would necessarily be contained in a container. Alternatively, the vessel in claim 19 of the '543 application could be a second container. Although the kit in instant claim 49 does not specifically recite a second container, it would have been prima facie obvious to one of ordinary skill in the art to include a container or vessel, in the kit of instant claim 49 so as to provide a container for conducting the molecular assay. The kits are therefore coextensive in scope and not patentably distinct from each other. The use for a kit is given no patentable weight. It is noted that the instructions in each kit are given no patentable weight as they provide an intended use for the claimed kits.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

27. Claim 49 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12, 13, 17, and 18 of copending Application No. 11/138,543 in view of Ahern. Claim 49 of the instant application is drawn to a

kit that comprises a reagent for suppressing the interference of a masking agent on a molecular assay and instructions for use. As defined by the specification such a reagent includes a divalent metal chelator, such as EDTA, EGTA, or BAPTA and/or a chelator enhancing component, such as lithium chloride, guanidine, sodium thiocyanate, sodium salicylate, and sodium perchlorate. Such a reagent can also include an enzyme inactivating component, such as manganese chloride, sarkosyl, and SDS. Claims 12 and 18 of the '543 application are drawn to a preservative composition comprising an amount of a divalent metal chelator, such as EDTA, EGTA, or BAPTA, in the range of about .001M to 2 M, or more specifically at least .01M; and a chelator enhancing component, such as lithium chloride, guanidinium chloride, guanidinium thiocyanate, sodium thiocyanate, sodium salicylate, and sodium perchlorate, in the range of from about 0.1M to 10 M, more specifically at least 1 M. Claims 13 and 17 are further drawn the composition containing an enzyme inactivating component, such as manganese chloride, sarkosyl, and SDS, in the range of up to 5% molar concentration. As such, the reagent in the kit of instant claim 49 and the composition of claims 12, 13, 17, 18 of the '543 application are coextensive in scope. Claims 12, 13, 17, and 18 of the '543 application do not recite packaging the composition in kit format, however Ahern teaches that providing reagents and products in kit format offers scientists the opportunity to better manage their time, and that such kits are convenient. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to package the reagent composition of the '543 application in kit format for the purposes of providing premade reagents which are convenient and will save researchers time, as taught by Ahern. It is noted that the "use for" the kit carries no patentable weight.

This is a provisional obviousness-type double patenting rejection.

***Conclusion***

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

29. No claims are allowable over the cited prior art.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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